



MERRIMACK COLLEGE

Faculty and Student Research FAQ's

Frequently Asked Questions Related to Human Participant Research and the COVID-19 Global Emergency

Last Updated March 24, 2020

Merrimack College continues to closely follow and respond to the COVID-19 global pandemic. These FAQs contain information about COVID-19 as it relates to the conduct of research and sponsored projects. For specific questions or concerns about your research project, please contact:

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For specific information pertaining to the Merrimack College Institutional Review Board (IRB) contact irb@merrimack.edu.

I. Internal Funding Sources (Merrimack College)

All pending or new internal grant awards for summer 2020 or AY 2021 are currently suspended until further notice. This includes the Provost Innovation Fund, SCURCA, CETL Faculty Fellowship, and Zampell Family Faculty Fellowship. More information on these grant programs will be provided in the following weeks but even if on-campus activities resume in the foreseeable future, we expect that these internal grant programs will remain suspended for AY 2021.

II. Suspension of Select Human Subjects Research

(Funded and non-funded research)

Given the reality of the COVID-19 global outbreak, Merrimack College is calling for all human subject research that includes any and all person-to-person contact to be immediately suspended until further notice. Failure to comply will result in the research being considered as non-compliant with the institution. The Merrimack IRB will continue to follow the College guidelines on this matter.

Are all aspects of research studies involving Human Subjects suspended?

No. Only human subject research that includes any and all person-to-person contact such as on-site interviews, physiological or psychological measurements, direct or onsite interventions or tests of any kind, behavioral manipulations, or similar face-to-face interactions. This suspension does not include:

- Research using virtual surveys (e.g., SONOS, MTurk) or analysis of data that includes no person-to-person contact with study participants
- Research where the person-to-person contact was completed and the researchers are now in the analysis or data preparation phase
- Studies being planned, in process, or completed that are in the preparation or writing phase

Can I alter person-to-person interactions related to my research studies involving Human Subjects?

Possibly. Currently approved protocols may be modified if investigators submit and are approved for a revised methodology involving virtual data collection or interventions. All modifications will be reviewed and approved in accordance with IRB and current suspension policies.

What is the procedure for altering a study or certain elements of a study?

Researchers may need to modify their procedures to replace in-person study visits with “remote” options for questionnaires, surveys, check-ins, screening, and consenting. These changes must be approved in advance by the Merrimack College Institutional Review Board (IRB) as a modification to the study. If you have any questions about whether a remote option is possible contact the Merrimack College IRB (irb@merrimack.edu). The IRB Committee will prioritize these modifications.

May I continue to collect data and follow-up with subjects by telephone when in-person data collection has been suspended?

Yes. There is no increased risk to subjects relating to COVID-19 when remote interaction occurs. However, researchers who wish to make any modifications, such as switching to telephone

instead of face-to-face interviews, need to submit a modification to be approved on a case-by-case basis.

May I continue conducting telephone screening of potential subjects?

Yes, if you have existing IRB approval for telephone interviews, there is no need to submit a modification. There is no increased risk to subjects relating to COVID-19.

May I conduct home visits to collect data in studies involving any participant?

No. While the real or potential risk to participants of traveling to a research site and aggregation at the site may be absent from home visits, there may still be risks of transmission of COVID-19.

Do I need approval from the IRB for communications to study subjects explaining the suspension in activities?

Possibly. Depending on the interactive component of the study (interviews versus in person interventions) the notification process may differ. Once a modification to move from in person to virtual, or to suspend it, is submitted to the IRB, then investigators can inform participants of that change and renew consent to participate based on the new format. However, if the project involved personal interaction with an intervention, the project would need to be suspended until it is deemed safe to interact. Notification of this suspension of the project could be sent immediately with consideration of policies of the host facility (if the study is being conducted in a school, institution, or other community-based venue) in regards to shut downs and other security measures. It is prudent to follow the 'most strict' guidelines provided when working with an outside agency. When in doubt, reach out to IRB for assistance and guidance.

What if my study doesn't clearly fall into any of these categories?

You should indicate what you think is the ethical basis for pausing or continuing the study in your response to IRB. If you state that as the Principal Investigator (PI), you believe that there is no increased potential or perceived risk from COVID-19, you may be able continue the study pending IRB review. Contact the Merrimack College IRB (irb@merrimack.edu) to find out the status of your particular study.

May I enroll new subjects on existing studies?

If your study involves any face-to-face interaction, then new participants cannot be enrolled until this suspension is lifted. If your study is virtual, then you may continue enrolling new participants. If you are unsure, please contact the Merrimack College IRB (irb@merrimack.edu) to find out the status of your particular study.

May I enroll new subjects while the IRB is making the determination whether to keep enrollment open?

No. If your study involves any face-to-face interaction, then new participants cannot be enrolled until this suspension is lifted. However, if your study is virtual, then you may continue enrolling new participants. If you are unsure, please contact the Merrimack College IRB (irb@merrimack.edu) to find out the status of your particular study.

May I initiate a new trial during the COVID-19 suspension?

This depends upon the type of study. The Merrimack College IRB Committee will continue to review and approve submissions. However, for studies that are newly approved and involve face-to-face interactions, the IRB will explicitly state that enrollment cannot start until after the suspension is lifted.

If I am suspending my study and it has an external IRB, do I need to notify that IRB of Record in addition to responding to the questions from the Merrimack College IRB?

Yes, as soon as possible. The regulations allow implementation of a change to study procedures without prospective IRB approval when it is necessary to avoid imminent hazards to subjects. The IRB of Record will need to approve resumption of study procedures.

III. Access to Laboratories and Facilities

In accordance with College’s Coronavirus Update (March 13th 2020), “...all non-essential personnel will be working from home. All in-person internal meetings scheduled should be conducted remotely and should be kept on schedule. The campus will remain open and operational with a significantly reduced workforce. The goal of this reduction in workforce is to lower social density on campus and increase social distancing”. No outside visitors or tours will be allowed.

Can I and/or my research assistant (student) access my lab and to continue to work on research there?

With Permission. You may be able to access your lab according to College policies but this must be approved beforehand by speaking with the dean of your School who will then communicate it through the necessary channels. All students will be prohibited from academic buildings (including Labs), residence halls (excluding special cases in effect), and all other places on campus.

IV. Grant-Funded Human Subjects Research

Should the National Institutes of Health (NIH) or other sponsors (government, industry, or non-profit) be notified that select protocol activities or in-person visits of a funded research study will be suspended?

Yes. The Office of Sponsored Programs (OSP) will issue an institutional notification to NIH and other sponsors. Once the IRB Committee makes specific protocol determinations, the Principal Investigator (PI) should contact OSP to request the information concerning those protocols that will require a suspension. Any follow-up communication will be sent by OSP for all impacted grants. OSP will notify each PI of the notification prior to contacting the sponsor. Just as would happen for normal grant administration activities, all communication to external sponsors must

be issued from OSP to meet grant compliance. For questions concerning sponsored projects or studies, please contact OSP at research@merrimack.edu.

V. Grant Proposals and Applications

Can I still submit proposals in accordance with the Office of Sponsored Programs?

Yes. The Office of Sponsored Programs (OSP) is continuing its' normal functions and you will be able to submit proposals, negotiate and accept awards, and issue subcontracts/subawards even if faculty and staff are working remotely. Faculty who have upcoming application deadlines should be in contact with OSP (research@merrimack.edu). OSP will adjust application preparation timelines accordingly.

If I have a proposal due and the College remains in suspended on-campus operations, will the awarding agency still accept my application?

Per the National Institutes of Health (NIH) [NOT-OD-20-082](#): When delays occur because the applicant or recipient organization is officially closed or unable to submit grant applications due to the effects of COVID-19, the NIH will consider accepting applications late, on a case-by-case basis, in accordance with the NIH Grants Policy Statement, Section 2.3.9, under the following circumstances:

- Institutions must submit applications or reports as soon as possible after reopening or resuming operations so that grant applications can be submitted, not to exceed the number of days the institution was officially closed or unable to submit grant applications.
- Institutions must submit a cover letter with the applications with enough detail about the delay so that NIH staff can make a determination whether circumstances justify accepting the application late.
- Institutions need not request advance permission to submit late due to this declared emergency.

Per [NIH NOT-OD-20-83](#): The NIH will consider accepting applications late, on a case-by-case basis. Recipients (OSP) must submit a cover letter with the application, outlining the fact that the institution is closed due to effects of COVID-19 so that NIH staff can document the delay. Recipients do not need to request advance permission to submit late due to a public health emergency-related delay.

Per [National Science Foundation \(NSF\)](#): Researchers or sponsored projects office staff from organizations that have been affected and are unable to meet stated NSF deadlines should contact the cognizant NSF program office to discuss the issue. NSF will consider extensions to the submission deadline on a case-by-case basis (and, in a few cases, on a program-by-program basis), understanding that it may be particularly difficult for individuals impacted to contact NSF.

See [NSF PAPPG Chapter I.F](#) for additional information on procedures for submitting such requests.

VI. Grant Management

How will the suspension in my research impact my grant expenditures?

All grant-related activities that are not affected by the suspension can continue to be charged as normal. The exception is student workers. If your project is impacted due to the lack of student workers or the suspension of human subjects, you should determine whether or not a No-Cost Extension (NCE) will be needed. Please contact OSP (research@merrimack.edu) to discuss your options. Additionally, there should not be a significant disengagement of the PI or other senior key personnel from affected projects. Current prior approval requirements remain in effect.

My grant may be impacted by the suspension, which could lead to delays in completing my study by the end of the project period. What should I do?

Most federal sponsors under the Office of Management and Budget (OMB) [guidance](#), including NIH, will allow for a one-time no cost extension for 12 months at the end of the project. Please discuss your specific project with OSP (research@merrimack.edu) who will provide guidance on the options available to you.

Should I notify the industry sponsor if my research activities are suspended on my clinical trial?

Yes. If the study needs to be suspended, the sponsor will need to be notified by OSP. Please contact OSP (research@merrimack.edu) to discuss your options.

I have a subcontract with another institution. Do I need to suspend that as well, if the suspension applies to my protocol at Merrimack College?

Yes. The same ethical issues relating to the changed risk/benefit ratio that apply to a Merrimack College site apply elsewhere.

As long as I am working remotely, can I continue to charge my grant?

Depends. If your study has not been suspended, then yes, the same “rules” apply to normal operations. If a certain percentage or level of effort of your salary is charged to the grant, the same will apply to working remotely. If your study is suspended, then you need to contact the funding agency as previously described.

Are travel cancellation costs due to COVID-19 allowable as direct costs to a sponsored project?

Specific federal guidance on this topic is not yet available. If Merrimack College’s policies, including those developed for COVID-19, allows for travel cancellation costs to be charged to intuitional fund sources, then the same should apply to sponsored projects to ensure consistent charging practices.

Will agencies consider longer no-cost time extensions if they are needed to finish a project after disruption?

Researchers should document the actual impact of COVID-19 on the progress of their grants to provide substantiation for any future no-cost time extension requests. It is not known at this time if agencies will consider longer-than-normal no-cost time extensions or multiple no-cost time extensions in this situation, but no-cost time extensions covered under expanded authorities will still be available for federal awards. Contact the Office of Sponsored Programs (research@merrimack.edu) who will contact the sponsor as soon as you are aware of a delay.

I have a progress report due in the near-term and my study is impacted by the suspension. Should I include information relating to the suspension in my progress report?

Yes. If your study is impacted, contact the Office of Sponsored Programs (research@merrimack.edu) as they will provide you with guidance on how and where this should be included in your progress report and what information that should be included (i.e., in Section F.2 of a NIH RPPR).

More Questions? Who to Contact?

Research and grant-related questions: Office of Sponsored Programs, research@merrimack.edu or (978) 837-5611

IRB Committee or IRB Chair: irb@merrimack.edu

Merrimack College Task Force: taskforce@merrimack.edu

External Resources

Some federal agencies have released specific guidance, while others have not as yet. Here are links to sources of information regarding COVID-19 responses:

Council on Governmental Regulations (COGR)

- [Institutional and Agency Responses to COVID-19 and Additional Resources](#)
- [COGR's FAQs Regarding COVID-19's Impact on Federal Awards](#)

National Institutes of Health (NIH)

- [Coronavirus Disease 2019 \(COVID-19\): Information for NIH Applicants and Recipients](#)
- [NOT-OD-20-083: General Frequently Asked Questions \(FAQs\) – Proposal Submission and Award Management Related to COVID-19](#)
- [NIH Extramural Response to Natural Disasters and Other Emergencies](#)
- [NIH Late Application Policy](#)
- [NIH Guidance on Travel and Meetings](#)

National Science Foundation

- [NSF FAQs for Coronavirus 2019 \(COVID-19\)](#)
- [NSF News on COVID-19](#)

Office of Management and Budget (OMB)

- [Administrative Relief for Recipients and Applicants of Federal Financial Assistance Directly Impacted by the Novel Coronavirus \(COVID-19\)](#)

Suggestions for Laboratory Operations

Prevention:

The overarching goal of the Merrimack College's actions is to minimize the risk of the spread of COVID-19 and to safeguard the health and safety of the Merrimack community. At this time, all are encouraged to practice social distancing ("maintaining distance, approximately 6 feet or 2 meters, from others when possible"). The following information may also be helpful as the COVID-19 crisis continues or changes.

- Consider implementing staggered schedules so that researchers can avoid close contact.
- Take basic [preventative measures](#) to avoid exposure to or infection from COVID-19, including:
 - Wash your hands often with soap and water for at least 20 seconds.
 - Stay home if you are sick.
 - Disinfect common laboratory areas and frequently touched surfaces (e.g. doorknobs, sink handles, freezer doors, fume hood sashes, telephones).
- Refer to the Merrimack College COVID-19 Task Force website <https://www.merrimack.edu/health-alerts/> for the recent updates.
- No tours and visitors.

Personnel:

- Make sure your faculty colleagues and students know what to do if operations remain suspended or if circumstances change.
- Remind your lab personnel of your communication plan to ensure all are informed; if you do not have such a plan in place, we urge you to create one.

Plan Your Research:

- Identify procedures and processes which require regular personnel attention (e.g. cell culture maintenance, animal care, etc.).
- Access and prioritize critical laboratory activities.
- Identify any research experiments that can be scaled back or delayed.
- If you are carrying out a long-term experiment and if it is possible to freeze or otherwise capture samples at specific steps, you might consider doing this more often.
- If you haven't already, in the future, cross-train research staff to fill in for others who may be out sick or unable to come to work.
- Ensure staff have the appropriate training.
- Document critical operating procedures.
- Coordinate with colleague who have similar research activities to identify ways to ensure coverage of critical activities.

- Maintain a sufficient inventory of critical supplies that may be impacted by global shipping delays.
- Communicate the need to avoid performing high-risk procedures alone. If working alone is permitted, ensure a notification procedure is in place.
- Ensure that high-risk materials, such as biohazards or chemicals are secured and freezers are labeled with emergency contact information.
- If some things can be carried out remotely such as data analysis, literature reviews etc., ensure that personnel have remote access to such information.
- If any of these steps generate unexpected costs, be sure to document the unanticipated costs for potential recovery.